K023449

JAN 1 3 2003

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS: NON-INVASIVE PATIENT FIXATION SYSTEM

General Information

Proprietary Name:	Non-Invasive Patient Fixation System
Common Name:	Patient Fixation
Classification Name(s):	System, Radiation Therapy, Charged Particle, Medical
Classification Code(s):	90LHN
Submitter:	Stryker Corporation Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Kelli J. Bitterburg Regulatory Affairs Associate Phone: 616-323-7700 x4026 Fax: 616-324-5454
Summary Preparation Date:	October 14, 2002

Summary of Safety and Effectiveness

The Leibinger system for non-invasive fixation is intended for patient positioning and immobilization, stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets.

The Stryker Non-Invasive Patient Fixation System is equivalent in intended use, safety, and effectiveness to existing patient fixation systems being marketed by companies such as Stryker, BrainLab and Medical Intelligence. It does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Non-Invasive Patient Fixation System is substantially equivalent to these existing devices.

Kelli J. Bitterburg
Regulatory Affairs Associate
October 14, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2003

Ms. Kelli J. Bitterburg
Regulatory Affairs Associate
Stryker Leibinger
4100 East Milham Avenue
KALAMAZOO MI 49001

Re: K023449
Trade/Device Name: Non-Invasive Patient Fixation System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle Radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 15, 2002
Received: October 16, 2002

Dear Ms. Bitterburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K023449

Device Name: Non-Invasive Patient Fixation System

Indication for Use:

The Leibinger system for non-invasive fixation is intended for patient positioning and immobilization, stereotactic diagnostic localization and stereotactic radiotherapy of cranial targets.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023449